

Remarks

Claims 1-6, 8-19 and 22 are pending in the present application. Claims 1-6, 8-19 and 22 are rejected. By the present amendment, claims 1, 3, 6, 10 and 12 are amended and claims 8, 13, 15 and 17 are cancelled.

Objection to the Drawings

In the Office Action, the drawings were objected to under 37 CFR 1.83(a). In support, it is asserted "the 'trigger unit' recited in claim 6 must be shown or the feature canceled from the claims."

Claim 6 is amended herein and "trigger unit" has been replaced with --button--, which is illustrated in Figs. 2a and 3a by reference numeral "11". No new matter has been added. In view of the present amendment, Applicants submit the drawings are in compliance with the statute and respectfully request that the objection be withdrawn.

Rejections Pursuant to 35 U.S.C. §102(b)

Also in the Office Action, claims 1-4, 8-12, 14-16 and 18 are rejected under 35 U.S.C. §102(b) as being anticipated by Ogura et al. (U.S. Patent No. 5,364,533).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Claim 8 is cancelled herein and its subject matter has been incorporated into claims 1 and 10, which claims are also amended herein and each recite, *inter alia*, a hollow body, a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone, and a plunger configured to be actuated within the hollow body, wherein upon actuation the plunger is configured to detach the second zone from the first zone and press the second zone against a wall of the hollow body to discharge the separated plasma through an outlet of the device. Claims 13, 15 and 17 are cancelled herein and their subject matter has been incorporated into amended claim 12 that

recites a method for plasma separation and discharge comprising, *inter alia*, providing a device comprising: a hollow body, a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone, and a plunger configured to be actuated within the hollow body. The method further comprises actuating the plunger to detach the second zone from the first zone and press the second zone against a wall of the hollow body, and discharging the separated plasma through an outlet. No new matter has been added.

In accordance with the various embodiments described, the present invention can provide for the release of the plasma and the separation of the plasma from blood, which according to the invention, are carried out as two separate successive processes. Thus, it is possible to accelerate plasma collection without having to apply pressure on the sample during the separation process. According to the present invention, the plasma is released substantially only by means of an action on the second zone of the separation element whereby this process can be accelerated in any desired manner (e.g., by overpressure, negative pressure, or elution processes, etc.). The plasma separation step is substantially independent of this process and occurs independently of the release process and can, for example, also be accelerated by capillary forces which act inside the first zone of the separation element. See para. [0020]. In accordance with the present invention, the discharge unit does not act on the separation fleece (where red blood cells are retained) because such action would possibly destroy the cells causing hemolysis and possibly setting haemoglobin free which would then infiltrate the plasma in the transport fleece and turn it red, which is to be avoided.

In the Office Action, with reference to Figs. 9 and 10, it is asserted Ogura et al. disclose a device for isolating plasma from a blood sample as well as the method for using the device to isolate plasma. Also in the Office Action, it is asserted the device comprises a first zone comprising a separation fleece 24 and a second zone comprising a transport fleece 29. The manner of using the embodiment shown in Figs. 9 and 10 is said to be similar to that of the fourth or fifth embodiment (col. 10, lines 22-35).

Accordingly, when it is intended to collect blood in the cylinder 23a of the injector 23, the suction port 28a of the vessel 28 is first immersed in blood stored in another vessel. Then, the plunger 23b is pulled out to suck the blood from the column 27 into the cylinder 23a. While the blood passes through the blood cell separating layer 24, the serum and plasma components are selectively separated from the blood and sucked in the cylinder 23a. (col. 9, lines 30-42). On the contrary, if the required amount of blood sample stored in the cylinder 23a of the syringe 23 is ejected by the plunger 23b, it is then possible to feed only the serum and plasma components separated from the blood sample through the blood cell separating layer 24 in the column 27 to a sample vessel. (col. 9, lines 42-48).

Either way, contrary to the present invention, Ogura et al. describe a discharge unit configured to act on both a first and second zone simultaneously. Ogura et al. cannot be said to teach a device and method for separating and discharging plasma, nor a system for detecting analytes in blood, each comprising, *inter alia*, a hollow body and a plunger configured to be actuated within the hollow body, wherein upon actuation the plunger is configured to detach the second zone from the first zone and press the second zone against a wall of the hollow body to discharge the separated plasma through an outlet of the device. Also, keep plate 29 is not a transport fleece.

Ogura et al. do not describe the subject matter of amended independent claims 1, 10 and 12 and, therefore, cannot be relied upon in support of the instant rejections. Claims 2-4, 9, 11, 14, 16 and 18 contain all of the limitations of the base claim from which they depend. Accordingly, applicants respectfully request the rejection be withdrawn.

Also in the Office Action, claims 1, 2, 4, 6, 9-14, 16, 18, 19 and 22 are rejected under 35 U.S.C. §102(b) as being anticipated by Kloepfer (U.S. Patent No. 4,883,764). It is asserted in the Office Action, in support of the instant rejection, that Kloepfer discloses a test strip comprising a separation member 16 and a recipient member 20.

To separate plasma from whole blood, a volume of blood . . . is applied to the separation member 16. Once separation is completed, the separation member is cut from the test strip to prevent contamination and the separated plasma is eluted from the recipient member 20 using a discharge unit in the form of a buffer solution.

Kloepfer cannot be said to teach the subject matter of the amended claims 1, 10 and 12. More specifically, Kloepfer does not in any way describe a device and method for separating and discharging plasma, nor a system for detecting analytes in blood comprising, *inter alia*, a hollow body and a plunger configured to be actuated within the hollow body, wherein upon actuation the plunger is configured to detach the second zone from the first zone and press the second zone against a wall of the hollow body to discharge the separated plasma through an outlet of the device. Accordingly, applicants respectfully request that the rejection be withdrawn.

Rejections Pursuant to 35 U.S.C. §103(a)

Also in the Office Action, claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Ogura et al. and claim 5 is rejected under §103(a) as being unpatentable over Kloepfer. In support of these rejections, it is asserted that with respect to Ogura et al. it would have been obvious to one of ordinary skill in the art to position the syringe at the bottom of the fleece and utilize negative pressure to separate plasma if one desires a pulling motion rather than a pushing motion to actuate the plunger of the syringe. Also, with respect to Kloepfer, although the reference does not disclose that the detachment of the separation member and the recipient member is accomplished by a rotating movement, the reference discloses that the separation member and the recipient member are separated by a scored perforation, and it is asserted that it is well known in the art to rip a perforated score line by applying a torque/rotating motion. The Examiner further concluded that it is apparent or obvious that the test strip disclosed by Kloepfer is configured to rotate about 90 degrees.

To establish a *prima facie* case of obviousness, *inter alia*, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Claim 17 is dependent upon claim 12, and claim 5 is ultimately dependent on claim 1 and, therefore, contain all of the limitations of that claim. As noted above, neither Ogura et al. nor Kloepfer teach or suggest the subject matter of amended claims 1 and 12 - providing a device comprising a hollow body and a plunger, and actuating the plunger to detach the second zone from the first zone and press the second zone against the wall of the hollow body. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. MPEP 2143.03 (*citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Accordingly, in view of the amendments made herein, Ogura et al. and Kloepfer cannot be relied upon in support of the instant rejections. Applicants respectfully request that the rejections be withdrawn.

Conclusion

Applicants have filed a complete response to the outstanding Office Action and respectfully submit that, in view of the above amendments and remarks, the application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
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